TAB V - 510(K) SUMMARY PAGE 1

510(K) SUMMARY

ImaCor Zura system with ClariTEE probe

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

ImaCor Inc
50 Charles Lindbergh Blvd
Suite 200
Uniondale, NY 11553
Phone: (516) 393-0970
Facsimile: (516) 393-0969
Contact Person: Richard C. Lanzillotto
Date Prepared: January 13, 2010

Name of Device and Name/Address of Sponsor

ImaCor Zura system with ClariTEE probe

ImaCor Inc
50 Charles Lindbergh Blvd
Suite 200
Uniondale, NY 11553

Common or Usual Name

Transesophageal Echo Imaging System

Classification Name

Ultrasonic Pulsed Doppler Imaging System (892.1550) Ultrasonic Pulsed Echo Imaging System (892.1560) with a Diagnostic Ultrasonic Transducer
(892.1570) or Echocardiograph (870.2330)

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Product Codes
IYN, IYO, DXK, ITX,

Device Class
II

Predicate Devices
ImaCor Zura (K080223)
Ultrasonix Medical SonixTouch with TEEIMA transducer (K083095)
Ultrasonix Medical Modulo Ultrasound Scanner (K042326)

Intended Use / Indications for Use

The intended use of the ImaCor Zura with ClariTEE is identical to that of the ImaCor Zura (K080223).

The ImaCor Zura with ClariTEE probe is intended for use in the episodic assessment of cardiac function using transesophageal echocardiography (TEE).

The ImaCor Zura TEE System is indicated for use in clinical settings, including long term settings such as the ICU, for an indwelling time period not to exceed 72 hours.

Technological Characteristics

The ImaCor Zura system with ClariTEE probe consists of three main components:

1. Ultrasound Machine:
A TEE predicate device optimized for use with ImaCor ClariTEE probe.

2. Ultrasound Probe (ClariTEE formerly known as the Blue Probe in K080223):
A miniaturized TEE probe optimized for longer dwell time relative to standard TEE probes enables use in longer term clinical settings such as the ICU. The probe distal tip is flexed upward transiently to obtain standard TEE images.

3. Ultrasound Imaging Software:

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The software controls standard ultrasound machine functions such as imaging, recording and measuring. Continuous imaging is limited by a 20 minute software interlock should the operator mistakenly leave the machine in continuous imaging mode, thus limiting the potential unintentional exposure of the patient's mucosal tissue to acoustic energy. Maximum probe face temperature is limited according to FDA consensus standard IEC 60601-2-37.

Latest software version enables two modes of operation; type B and color flow Doppler. The subsequent version cleared for marketing under K080223 enabled type B only.

Performance Data

Performance data using a flow phantom demonstrates the effectiveness of the design modification; the addition of a color flow mode of operation to support the assessment of cardiac function. All other aspects of the intended use were verified pursuant to the original 510k for the ImaCor Zura (K080223).

Substantial Equivalence

The ImaCor Zura System with ClariTEE probe is as safe and effective as the predicate devices. The ImaCor Zura with ClariTEE probe has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. The minor technological differences between the ImaCor Zura with ClariTEE probe and its predicate devices raise no new issues of safety or effectiveness. Performance data demonstrate that the ImaCor Zura is as safe and effective as the predicates. Thus, the ImaCor Zura with ClariTEE probe is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

JUN 25 2010

Mr. Richard Lanzillotto
Director of Regulatory Affairs
ImaCor, Inc.
50 Charles Lindbergh Blvd., Suite 200
UNIONDALE NY 11553

Re: K100989
Trade/Device Name: ImaCor Zura system with ClariTEE probe
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, and ITX
Dated: June 15, 2010
Received: June 16, 2010

Dear Mr. Lanzillotto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the ImaCor Zura system with ClariTEE probe, as described in your premarket notification:

Transducer Model Number

ClariTEE probe

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

If you have any questions regarding the content of this letter, please contact Shahram Vaezy at (301) 796-6242.

Sincerely yours,

Donald St. Pierre
Acting Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure(s)

ImaCor

04/09/2010

Zura system 510 K for software modification

Indications for Use Statement

510(k) Number (if known):_____

Device Name: ImaCor Zura system with ClariTEE probe

Indications for Use:

The ImaCor Zura system with ClariTEE probe is intended for use in the episodic assessment of cardiac function using transesophageal echocardiography. It is indicated for use in clinical settings, including long term settings such as the ICU, for an indwelling time period not to exceed 72 hours. The ImaCor Zura system with ClariTEE probe is not intended for pediatric use

Prescription Use __√___ (Part 21 C.F.R. 801 Subpart D)

AND/OR

Over-The-Counter Use____ (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100989

TAB IV - INDICATIONS FOR USE STATEMENT

Indications for Use Statement

510(k) Number (if known):___K100989

Device Name: ImaCor **Zura system**
Indications for Use:

The ImaCor Zura system is intended for use in the episodic assessment of cardiac function using transesophageal echocardiography. It is indicated for use in clinical settings, including long term settings such as the ICU, for an indwelling time period not to exceed 72 hours. The ImaCor system is not intended for pediatric use

General	Specific	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal Imaging & Other								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)	P				N		
	Intracardiac							
	Other							
Peripheral Vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Prescription Use __√___ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Page ____ of ____

(Division Sign-Off)
Division of Radiological Devices
Office of In Vitro Diagnostic Device Evaluation and Safety

510K K100989

Indications for Use Statement

510(k) Number (if known):___K100989

Device Name: ImaCor **ClariTEE probe**
Indications for Use:

The ImaCor ClariTEE probe is intended for use in the episodic assessment of cardiac function using transesophageal echocardiography. It is indicated for use in clinical settings, including long term settings such as the ICU, for an indwelling time period not to exceed 72 hours. The ClariTEE probe is not intended for pediatric use.

General	Specific	B	M	PWD	CWD	Color Doppler	Combined (Specify)	Other (Specify)
Ophthalmic								
Fetal Imaging & Other								
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Intravascular (Cardiac)							
	Trans-esoph (Cardiac)	P				N		
	Intracardiac							
	Other							
Peripheral Vessel								

N = new indication; P = previously cleared by FDA; E = added under this appendix

Prescription Use __√___ AND/OR Over-The-Counter Use____

(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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Division of Radiological Devices
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510K K100989